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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,875	06/27/2003	Harish Makker	27542	7856

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EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,875

Applicant(s)

MAKKER ET AL.

Examiner

Christopher P Bruenjes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-17 in the reply filed on March 28, 2005 is acknowledged.
2. Claims 18-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 28, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the limitation "a novel enhanced tubular means for inserting an intraocular lens through a small incision

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into an eye" renders the claim vague and indefinite because it is not understood if the limitation is intended to invoke 35 U.S.C. 112 sixth paragraph means-plus-function, or merely claiming a tube with an intended use for the tube. Also the limitation "tube means" is vague and indefinite for the same reasons set forth above.

Claims 2-17 are rejected as dependent on claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al (USPN 5,803,925) in view of Luthra et al (USPN 6,287,707).

Yang et al teaches a novel enhanced tubular means for inserting an intraocular lens through a small incision into an eye, comprising, in combination: a hollow tube means including an interior wall defining a hollow space through which an intraocular lens may be passed from the hollow space into an eye and a lubricity enhancing component covalently bonded to the hollow tube at the interior wall in an amount effective to facilitate the passage of the intraocular lens through the hollow space (see abstract). Regarding claim 8, the lubricity enhancing component is hydrophilic such as polyethylene glycol, which is an ethylene oxide component (col.4, 1.60-65). Regarding claim 15, the lubricity enhancing component is effective to reduce the force needed to pass the intraocular lens through the hollow space relative to the force needed to pass an identical intraocular lens through the hollow space of a similar apparatus without the lubricity enhancing component (col.3, 1.26-30). Regarding claim 16, the tubular means further comprising a loading portion coupled to the hollow tube and

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sized and adapted to receive an intraocular lens for passage into the hollow space (col.3, 1.45-67). Regarding claim 17, the lubricity enhancing component is covalently bonded to the loading portion in an amount effective to at least assist in facilitating the passage of said intraocular lens into said hollow space (col.3, 1.50-54).

Yang et al teach that the lubricity enhancing component precursor includes polyethylene glycol, which is a polyethylene oxide component, but fails to teach that the precursor also includes a substituent component for reducing hydrolysis of said lubricity enhancing component relative to an identical lubricity enhancing component without the at least one improved substituent component or an additional substituent component effective to covalently bond with at least one of the precursor component and the hollow tube. However, Luthra et al teach that polyethylene glycol coatings such as the coating of Yang et al provide medical devices such as the tubular means of Yang et al with a good biocompatible lubricious hydrophilic coating (col.1, 1.38-42). However, Luthra also teach that a preferred polyethylene glycol coating for medical devices is a methoxy polyethylene glycol methacrylate (col.2, 1.50-52). One of ordinary skill in the art would have recognized that Yang et al and Luthra et al are analogous insofar as both references are

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concerned with forming biocompatible lubricious hydrophilic coatings on medical devices for insertion in human bodies.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that methoxy polyethylene glycol methacrylate of Luthra et al is a well known polyethylene glycol lubricious coating in the art of medical devices for insertion in human bodies and is substituted for the generic polyethylene glycol lubricious hydrophilic coating of Yang et al, because methoxy polyethylene glycol methacrylates are known in the art to be preferred for the specific problem encountered in Yang et al, as taught by Luthra et al.

Regarding the limitation of claim that "the lubricity enhancing component includes at least one improved substituent component for reducing hydrolysis of said lubricity enhancing component relative to an identical lubricity enhancing component without the at least one improved substituent component", Yang et al and Luthra et al taken as a whole teach the at least one improved substituent component claimed and the fact that the substituent component reduces hydrolysis is a latent property of the substituent component. Therefore, the references as a whole teach the limitation since the mere recognition of latent

properties in the prior art does not render nonobvious an otherwise known invention.

Regarding claim 2, the substituent component is methoxy, which is not hydroxy.

Regarding claims 3-6, the substituent component is methoxy, which is a hydrocarbyl group having 1 carbon atom and is also an alkoxy group having 1 carbon atom.

Regarding claim 7, Yang et al and Luthra et al taken as a whole teach the at least one improved substituent component is preferably methoxy over hydroxy and the fact that methoxy rather than hydroxy as the substituent component reduces hydrolysis is a latent property of the methoxy substituent component. Therefore, the references as a whole teach the limitation since the mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.

Regarding claim 9, the methacrylate portion of the precursor taught in Luthra et al is an additional substituent component as claimed, and the fact that methacrylate is effective to covalently bond with at least one of the precursor component and the hollow tube is a latent property.

Regarding claims 10 and 12, the additional substituent component methacrylate is an ethylenically unsaturated group from the class of methacrylic groups.

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Regarding claim 11, polyethylene glycol of the precursor is an ethylene oxide component, which is an alkylene oxide component.

Regarding claim 13, the precursor of Luthra et al is water soluble.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al (US 2002/0133072 A1); Guire (USPN 5,263,992); Graiver et al (USPN 5,429,839).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes


Examiner

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CPB

CPB

June 24, 2005


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772
6/23/05